

National Institutes of Health

Recombinant DNA Advisory Committee



USDA Regulation of Highly Pathogenic Avian Influenza (HPAI) H5N1 Research

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Safeguarding Animal Health



Authority

- **Animal Health Protection Act of 2002** –Authorizes the APHIS Administrator to regulate the interstate and international movement of any animal or article in order to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.
- **Agricultural Bioterrorism Act** – Authorizes the APHIS Administrator to regulate the possession, use and transfer of any animal or plant select agents or toxins in order to protect animal and plant health and their products.
- **9 CFR 122 – Organisms and Vectors** - Requirements for the permitting the import or interstate movement of organisms and vectors which may introduce or disseminate any contagious or infectious disease of animals (including poultry).
- **9 CFR 121 – Possession, Use, and Transfer of Select Agents and Toxins**



Guidelines

- Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- Agricultural Research Service (ARS) Manual 242.1, ARS Facilities Design Standards
- OIE (World Animal Health Organization) Manual of Diagnostics Tests and Vaccines for Terrestrial Animals

9 CFR 122 - Permitting

- USDA has a long history in permitting animal pathogens for import and interstate movement, prior to select agent regulations
- Have required BSL3/ABSL3 standards as outlined in BMBL along with enhancements as a permit condition
- Facility inspections to verify appropriate biosafety levels conducted prior to permit issuance



9 CFR 121 – Select Agent Regulations (SAR)

- HPAI as select agents
- Low Pathogenic Avian Influenza (LPAI) excluded from the SAR
- Consider H5 and H7 as HPAI unless tested otherwise per OIE Guidelines



HPAI Biosafety Enhancements

- Dependent on type of work
- Primary agriculture concern is release from containment
- Humans serve as fomites in virus transmission
- Containment features should account for failure scenarios
- In-vitro Diagnostics – BSL2 plus:
 - Clothing change to enter and leave the lab or
 - Full body Tyvek or jumpsuit or
 - Disposable wrap-around smock, arm covers, shoe covers, and
 - Personnel quarantine or restriction policy



HPAI Biosafety Enhancements cont.

- Personnel Quarantine Policy

- For work [in vitro, as well as in vivo] with HPAIV, APHIS requires entities to implement a personnel quarantine policy for visitors and staff. Entities must have, in place, a written policy prohibiting laboratory staff and visitors from having contact with susceptible avian species for a minimum of 5 days after the last possible contact with the HPAIV virus in BSL2 and BSL3/ABSL3 laboratories. The prohibition on contact with susceptible avian species includes, but is not limited to, contact with any pet birds, backyard poultry flocks, birds at county/state fairs, commercial poultry operations, zoological collections (i.e. zoos), and wild birds (e.g., ducks, geese). Entity's policy must require that employees and visitors read the policy, and acknowledge, by signature, their agreement to comply with that policy .



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HPAI Biosafety Enhancements cont.

- In-vitro laboratory work (virus propagation) – BSL3 plus:
 - Shower out of the facility (non-containment/containment boundary)
 - Personnel quarantine policy
 - Liquid effluents from the laboratory are heat or chemically treated prior to reaching public sewage
 - HEPA filtration of exhaust air

HPAI Biosafety Enhancements cont.

- In-vivo work with animal primary containment caging – ABSL3 plus:
 - Shower out of the facility (non-containment/containment boundary)
 - Personnel quarantine policy
 - Liquid effluents from the laboratory are heat or chemically treated prior to reaching public sewage
 - Solid animal wastes and tissues are heat treated

HPAI Biosafety Enhancements cont.

- ABSL3 plus cont.:
 - Bio-isolators are HEPA filtered out;
 - HEPA filtration of all exhaust air derived from the containment area
- In-vivo work with room as primary containment – BSL3Ag plus:
 - Personnel quarantine policy

USDA Approval of HPAI Work

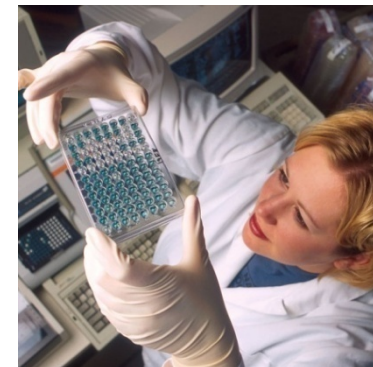
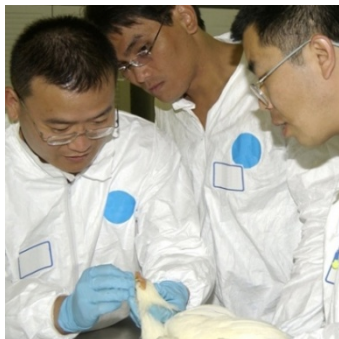
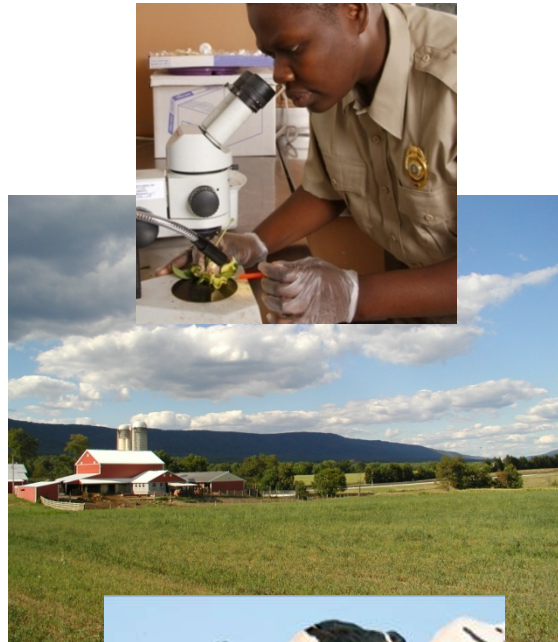
- Review Biosafety plan
 - Project protocol for type of work, duration of project, animal species if any, potential for restricted experiment work or exclusions needed
 - Standard Operating Procedures for PPE, personnel movement, animal containment, waste disposal, potential for cross contamination, floor plans, primary and secondary facility containment features, personnel quarantine



USDA Approval of HPAI Work cont.

- Inspection Results
 - Verify information from biosafety plan and SOP's
 - Verify facility and caging containment features
 - Provide report back to File Owner for review
- File owner issues approval once all other reviews for security and personnel are completed.

Questions?



Contact Information

- Agriculture Select Agent Program
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